

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.  
PELVIC REPAIR SYSTEMS  
PRODUCT LIABILITY LITIGATION

MDL No. 2327

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THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit  
Attached Hereto

MEMORANDUM OPINION AND ORDER  
(*Daubert* Motion re: Jaime L. Sepulveda-Toro, M.D.)

Pending before the court is the Motion to Limit the Opinions and Testimony of Jaime L. Sepulveda-Toro, M. D. [ECF No. 2014] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

**I. Background**

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”), among others.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara

J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.<sup>1</sup>

## II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and

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<sup>1</sup> The plaintiffs identified the Wave 1 cases affected by this Motion in their attached Exhibit A [ECF No. 2014-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or

remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated

firsthand.

### III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

*Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

#### **IV. Discussion**

Dr. Sepulveda-Toro is board-certified in obstetrics and gynecology. His practice focuses on treating female urinary incontinence and other pelvic floor disorders.

##### **a. Safety and Efficacy**

The plaintiffs challenge the reliability of Dr. Sepulveda-Toro's expert testimony about the safety and efficacy of the SUI and POP products at issue. Dr. Sepulveda-Toro's expert testimony is unreliable, the plaintiffs claim, because he agrees with an FDA classification that the plaintiffs believe is contradictory to his testimony, because he stopped using the products after they were removed from the market, and because he could not name the five-year studies on SUI products on which he relied during his deposition. Upon review, each of these arguments is wholly devoid of merit. I can easily reject the FDA classification argument because it is based on the plaintiffs' mischaracterization of Dr. Sepulveda-Toro's deposition testimony. The use argument is irrelevant because Dr. Sepulveda-Toro merely stopped using the products because they were not on the market, not because they were not safe or effective. The studies argument is meritless because the report includes citations to long-term studies, so it does not matter whether Dr. Sepulveda-Toro could recall the studies during his deposition. So the plaintiffs' Motion is **DENIED** on this point.

##### **b. Design**

The plaintiffs claim Dr. Sepulveda-Toro is not qualified to offer what they characterize as design opinions. But they do not explain or identify these opinions with sufficient specificity. This most recent wave of *Daubert* motions in this MDL is plagued with some confusion about what constitutes a design opinion. So some clarification is necessary before proceeding.

At first glance, it seems the plaintiffs want to prevent Dr. Sepulveda-Toro from providing any opinions that even mention the word “design.” But the mere utterance of a single word is not an incantation that transforms an opinion about one thing into something else.

A close, contextual reading of the transvaginal mesh cases where this issue has been raised before reveals the heart of the plaintiffs’ objections. In this motion—and several others—the plaintiffs argue that the expert at issue lacks the particularized skill, knowledge, experience, education, or training that is necessary to provide opinions about the process of designing a product. Opinions of this sort include, for example, opinions about pre-marketing product testing and product development. But upon review, I find Dr. Sepulveda-Toro has not expressed any opinions about the process of designing a product. So the plaintiffs’ Motion is **DENIED as moot** on this very limited issue.

### c. Warnings

The plaintiffs claim Dr. Sepulveda-Toro is not qualified to offer expert testimony about product warnings, which includes expert testimony about the

adequacy of the relevant Instructions for Use (“IFU”). According to the plaintiffs, Dr. Sepulveda-Toro is not an expert in the development of warnings labels and thus is not qualified to offer expert testimony about warnings. While an expert who is a gynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at \*14 (S.D. W. Va. Feb. 7, 2015). Dr. Sepulveda-Toro does not possess the additional expertise to offer expert testimony about what an IFU should or should not include.<sup>2</sup> Accordingly, Dr. Sepulveda-Toro’s expert testimony about these matters is **EXCLUDED**.

The plaintiffs also object to Dr. Sepulveda-Toro’s opinions on the adequacy of Ethicon’s brochures, which he says “allow a patient to construct a base to be used in the conversation about the procedure.” Sepulveda-Toro Report 18 [ECF No. 2014-2]. The court is doubtful of the relevance of such testimony given the usual application of the learned intermediary doctrine to cases in these MDLs. As the relevance of this

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<sup>2</sup> In relation to the expert testimony about the adequacy of the IFU, Ethicon claims Dr. Sepulveda-Toro is qualified to testify about whether certain risks were commonly known in the medical community. In my view, this is not the subject of the plaintiffs’ motion. The plaintiffs’ motion focuses on whether Dr. Sepulveda-Toro is qualified to offer expert testimony about what should be included in or what may be excluded from an IFU. So I offer no opinion on whether Dr. Sepulveda-Toro may testify about whether certain risks were common knowledge. However, an expert cannot testify about whether any risks should have been included in an IFU unless he or she possess additional expertise—expertise Dr. Sepulveda-Toro does not possess.

testimony will best be determined on a case-by-case basis applying the applicable state law, I **RESERVE** ruling on this point.

**d. Value of Explanted Materials**

The plaintiffs challenge Dr. Sepulveda-Toro's qualifications to opine that explanted mesh undergoes forces beyond those it would experience in an SUI or POP procedure. They argue that Dr. Sepulveda-Toro is unqualified to make this statement because he is not a pathologist. But Dr. Sepulveda-Toro has extensive experience studying the relevant part of the body, both through surgery and through the dissection of hundreds of cadaver specimens. He has also written a manual on dissection and how to make the best of specimens. Accordingly, I find Dr. Sepulveda-Toro sufficiently qualified to make the statements at issue here and **DENY** the Motion on this point.

The plaintiffs also challenge Dr. Sepulveda-Toro's qualifications to critique the plaintiffs' pathologists' testimony because he is not a pathologist himself. Without more specificity as to which opinions are being challenged, the court must **DENY** the Motion on this point.

**e. Medical Literature Support**

The plaintiffs object to Dr. Sepulveda-Toro's characterizations of the medical literature that allegedly supports his opinions on cytotoxicity, degradation, and inflammatory response. The court is without sufficient information at the time to judge the reliability of Dr. Sepulveda-Toro's methodology in considering the relevant

literature, and therefore **RESERVES** ruling until the evidence may be evaluated firsthand at trial.

**f. Gold Standard**

The plaintiffs seek to exclude Dr. Sepulveda-Toro's use of the phrase "gold standard" in describing the TVT. Ethicon represents that Dr. Sepulveda-Toro will not use the phrase at trial, so the Motion on this point is **DENIED as moot**.

**g. Defectiveness**

The plaintiffs also object to the reliability of Dr. Sepulveda-Toro's opinion that "[t]he long term data on TVT and TVT[-]O are also inconsistent with a theory that mechanical cut tape is defective." They claim that this statement is inconsistent with Dr. Sepulveda-Toro's other testimony describing the availability of certain types of studies and critique the literature he relied on. The court finds these objections insufficient to credibly call into question the reliability of Dr. Sepulveda-Toro's statement. The Motion is **DENIED** on this point.

**V. Recurring Issues**

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in**

**part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the

Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's

clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

*First*, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend*

*Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

*Second*, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

*Third*, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

*Fourth*, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

*Finally*, in some of the *Daubert* motions, without identifying the expert testimony to be excluded, the parties ask the court to prevent experts from offering

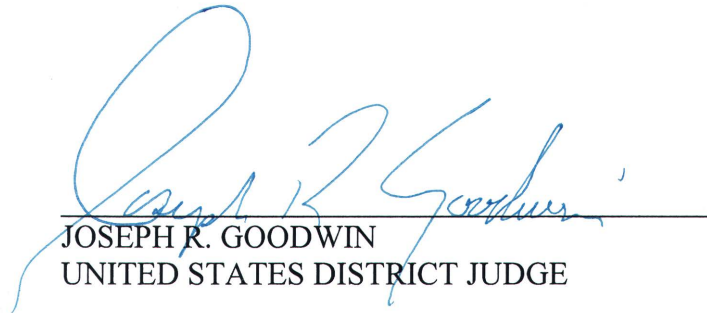
other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

**VI. Conclusion**

The court **DENIES in part, GRANTS in part**, and **RESERVES in part** the Motion to Limit the Opinions and Testimony of Jaime L. Sepulveda-Toro, M. D. [ECF No. 2014].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in Exhibit 1 attached to the Motion to Limit the Opinions and Testimony of Jaime L. Sepulveda-Toro, M. D. [ECF No. 2014].

ENTER: August 30, 2016



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE

# **EXHIBIT A**

**EXHIBIT A – SEPULVEDA-TORO DAUBERT MOTION**

**THIS DOCUMENT RELATES TO PLAINTIFFS:**

*Mary Cone*  
*Case No. 2:12-cv-00261*

*Dina Destefano-Raston*  
*Case No. 2:12-cv-01299*

*Nancy Hooper*  
*Case No. 2:12-cv-00493*

*Alfreda Lee*  
*Case No. 2:12-cv-01013*

*Romona Greer (deceased)*  
*Case No. 2:12-cv-00510*

*Jennifer Reyes*  
*Case No. 2:12-cv-00939*

*Carrie Smith*  
*Case No. 2:12-cv-00258*

*Beth Harter*  
*Case No. 2:12-cv-00737*

*Sheri Scholl*  
*Case No. 2:12-cv-00738*

*Margaret Stubblefield*  
*Case No. 2:12-cv-00842*

*Roberta Warmack*  
*Case No. 2:12-cv-01150*

*Jackie Frye*  
*Case No. 2:12-cv-01004*

*Dina Sanders Bennett*  
*Case No. 2:12-cv-00497*

*Joan Adams*  
*Case No. 2:12-cv-01203*

***Barbara Vignos-Ware***  
***Case No. 2:12-cv-00761***

***Fran Collins***  
***Case No. 2:12-cv-00931***

***Pamela Gray Wheeler***  
***Case No. 2:12-cv-00455***

***Deborah Lynn Joplin***  
***Case No. 2:12-cv-00787***

***Donna Shepherd***  
***Case No. 2:12-cv-00967***

***Paula Fisk***  
***Case No. 2:12-cv-00848***

***Teresa Georgilakis***  
***Case No. 2:12-cv-00829***

***Jennifer Sikes***  
***Case No. 2:12-cv-00501***

***Isabel Swint***  
***Case No. 2:12-cv-00786***

***Krystal Teasley***  
***Case No. 2:12-cv-00500***

***Susan Thaman (Reeves)***  
***Case No. 2:12-cv-00279***

***Kimberly Thomas (Wyatt)***  
***Case No. 2:12-cv-00499***

***Louise Grabowski***  
***Case No. 2:12-cv-00683***

***Cathy Warlick***  
***Case No. 2:12-cv-00276***